

**REMARKS**

**Claim Objection**

The Examiner has objected to Claim 86 for being unclear due to informalities. The Applicant has amended the claim to clarify its meaning in view of the Examiner's request.

**Rejection Under 35 USC § 101**

The Examiner has rejected pending Claim 86 for not being supported by a "specific, substantial and credible utility." The Applicants respectfully disagree. However, and solely to advance their business interests, the Applicant's have amended Claim 86 to better discern the Applicant's invention. In light of the present amendment the Applicants now believe that the Examiner's rejection is moot and respectfully request that the rejection be withdrawn.

**Rejection Under 35 USC § 112, first paragraph - Enablement**

Claim 86 has been rejected under 35 USC § 112, first paragraph, for containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains ... to make or use the invention." The Applicants respectfully disagree. It is the Applicants understanding that the specification need not recite every embodiment of an invention for a claim to issue. Rather (and it is preferred) only exemplary embodiments need be provided. The Applicants have met this burden of providing exemplary embodiments as prescribed by the USPTO with the specification as filed. Additionally, the Examiner stated, "such assays can be performed with any protein or polypeptide antigen" [current response, page 3]. Thus, by the Examiners admission, the current specification is enabling for a broad range of applications, as claimed. Still, and solely to advance the Applicant's business interests while reserving the right to prosecute the original or similar claims in the future, the Applicants have amended the claim to better define the metes and bounds of the present invention. In view of these reasons, the Applicants respectfully request that the rejection be withdrawn.

**Rejection Under 35 USC § 112, first paragraph – Written Description**

Claim 86 has been rejected under 35 USC § 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s) at the time of the application was filed, had possession of the claimed invention.” The Examiner argues that Claim 86 is to a genus and that the specification does not provide “sufficient distinguishing identifying characteristics of the genus.” The Examiner then lists numerous factors to be considered as identifying characteristics for a genus, which may be considered in combination or singularly. The Examiner then identifies a characteristic by which the genus recited by the claim can be distinguished, namely, antigenicity. In spite of the Examiner's identification of a distinguishing characteristic for the genus, the Examiner then proceeds to reject the claim for the lack of “sufficient recitation of distinguishing identifying characteristics.” For the forgoing reasons the Applicants believe that the present rejection is inappropriate and respectfully request that it be withdrawn.

Rejection Under 35 USC § 112, second paragraph

The Examiner has rejected Claim 86 for being indefinite for being dependent upon cancelled claims. The Applicants have amended the claim to remove any reference to other claims. In view of the amended claim the Applicants request the rejection be withdrawn.

Rejection Under 35 USC § 102(b)

Claim 86 is rejected under 35 USC § 102(b) as being anticipated by Vannier, et al. Vannier teaches an ELISA method for identifying antibodies from experimental samples using an ubiquitin-hFSHR fusion protein. However, Vannier does not teach fusion protein wherein ubiquitin is either i) fused to a single epitope-containing segment, the epitope-containing segment comprising two or more identical epitopes, ii) fused to two or more non-contiguous epitope-containing segments, each epitope-containing segment comprising one or more identical or non-identical epitopes, iii) fused to a single epitope-containing segment comprising two or more identical or non-identical epitopes, the epitope-containing segments being fused to the ubiquitin at fusion sites selected from the groups consisting of the N-terminus and an internal fusion site or, iv) fused to a single epitope-containing segment comprising one or more identical or non-identical epitopes, the epitope-containing segment being fused to ubiquitin at the N-terminus of the heat shock protein, wherein one or more epitopes are recognized by the antibody to be

detected, as recited in amended Claim 86. Therefore, the Applicants respectfully request that the rejection be withdrawn and the claim be passed to allowance.

Rejection Under 35 USC § 102(b)

Claim 86 is rejected under 35 USC § 102(b) as being anticipated by Loosfelt, et al. Loosfelt teaches screening antibodies to the thyrotropin receptor in an ELISA assay with ubiquitin fusion proteins. However, Loosfelt does not teach fusion protein wherein ubiquitin is either i) fused to a single epitope-containing segment, the epitope-containing segment comprising two or more identical epitopes, ii) fused to two or more non-contiguous epitope-containing segments, each epitope-containing segment comprising one or more identical or non-identical epitopes, iii) fused to a single epitope-containing segment comprising two or more identical or non-identical epitopes, the epitope-containing segments being fused to the ubiquitin at fusion sites selected from the groups consisting of the N-terminus and an internal fusion site or, iv) fused to a single epitope-containing segment comprising one or more identical or non-identical epitopes, the epitope-containing segment being fused to ubiquitin at the N-terminus of the heat shock protein, wherein one or more epitopes are recognized by the antibody to be detected, as recited in amended Claim 86. Therefore, the Applicants respectfully request that the rejection be withdrawn and the claim be passed to allowance.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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